September 26, 2002

MEMORANDUM TO: Samuel J. Collins, Director
Office of Nuclear Reactor Regulation

FROM: David C. Fischer, Senior Mechanical Engineer ***/RA/***
Mechanical & Civil Engineering Branch
Division of Engineering
Office of Nuclear Reactor Regulation

SUBJECT: DIFFERING PROFESSIONAL VIEW — RISK-INFORMED PART 50, OPTION 2

The purpose of this memorandum is to express my concern over a proposed rule aimed at risk-informing 10 CFR Part 50 (RIP-50) which is about to be issued for public comment. Since the mid-1980s, I have been actively involved with bringing risk insights into the regulatory process (e.g., risk-informing technical specifications, risk-informing inservice test requirements). I am a strong supporter of increased use of probabilistic risk assessments (PRAs) for regulatory activities in a manner that supports the Agency's Performance Goals. Since June 1999, I have been working on the RIP-50 Option 2 rule with the RIP-50 Option 2 Core Team. I was also actively involved with reviewing the related South Texas Project requests for exemptions from certain special treatment regulations and was a principal contributor to our safety evaluation which served as the basis for granting some of those exemptions. I take writing this memorandum to you very seriously and I do so only because I believe that the proposed rule, if ultimately issued in its current form and implemented, would not provide adequate protection of public health and safety.

Summary of Management's Current Approach for Option 2 Rulemaking

The current approach for risk-informing 10 CFR Part 50 relies on a "robust categorization process" to identify which safety-related components can be exempted from special treatment requirements (e.g., quality assurance, maintenance rule, inservice inspection, inservice testing, reporting). These components would, however, remain in the plant and would still be required to function under design-basis conditions.

The proposed rule identifies minimum high-level requirements for both the categorization and treatment processes. The staff has developed regulatory guidance related to the categorization process for Option 2. Licensees that choose to adopt 10 CFR 50.69 would be required to submit their categorization process to the NRC staff for review and approval prior to implementation. The proposed rule, as currently constructed, uses very high level treatment objectives to provide regulatory confidence that the safety-related components categorized as having low safety significance (RISC-3 components) will remain functional. The staff does not plan to develop regulatory guidance related to the treatment of RISC-3 SSCs. The licensee's treatment process will not be reviewed and approved by the staff prior to implementation. The proposed rule requires no information relative to the treatment of the RISC-3 SSCs.

The proposed rule relies on evaluations, such as sensitivity studies, to show that any potential change in core damage frequency (CDF) and large early release frequency (LERF) is small (i.e., potential change in risk that might result from any decrease in SSC capability/reliability as a result of reduced treatment being applied to RISC-3 SSCs). The proposed rule also requires that licensees provide the basis for the acceptability for these evaluations. For example, increasing the unreliability of all RISC-3 SSCs by a factor of 2 to 5 could, as stated in NEI-00-04, provide an indication of the potential trend in CDF and LERF, if there were a degradation in the performance of all low safety-significant SSCs. The factor of 2 to 5 is assumed to be appropriate because it is representative of the change in reliability between a mean value and an upper bound (95th percentile) for typical equipment reliability distributions.

The following is the proposed general high-level treatment objective to ensure the functionality of RISC-3 SSCs (there are other high-level requirements related to design control; procurement; inspection, maintenance, testing, and surveillance; and corrective action).

> "The licensee or applicant shall develop and implement processes to control the design; procurement; inspection, maintenance, testing, and surveillance; and corrective action for RISC-3 SSCs to provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety-related functions under design-basis conditions throughout their service life."

Management asserts that the rule should only specify <u>what</u> the NRC's expectations are related to RISC-3 SSCs as opposed to specifying <u>how</u> those expectations are to be satisfied. Management's position is that, as a matter of policy, such high-level treatment requirements provide the appropriate level of regulatory control, given the robustness of the categorization process and the low safety significance of the components. Management states that reliance on such high-level treatment requirements is consistent with Commission expectations. Furthermore, management states that these high-level treatment requirements, if effectively implemented by licensees, will provide reasonable confidence in the functionality of the RISC-3 SSCs.

At South Texas Project, the proof-of-concept plant for the Option 2 rulemaking effort, approximately 75% of the safety-related pumps and valves were categorized as having low safety significance (analogous to RISC-3 SSCs under Option 2). Examples of equipment categorized as LSS at South Texas Project include:

- diesel generator air start valves;
- main steam isolation valves;
- all feedwater system valves (including flow control and isolation valves);
- spent fuel pool pumps and valves;
- most RHR system valves;
- all (but one) valve in the service water system;
- reactor head vent throttle and isolation valves;
- most chemical, volume, and control system valves;
- HPSI and LPSI flowpath motor-operated valves (MOVs);
- all component cooling water MOVs;
- containment spray pumps and valves;
- most containment isolation valves (including 9 ISLOCA valves)
- centrifugal charging pumps

As you can see, RISC-3 SSCs are not limited to vents and drains and other unimportant components as some often characterize them. Many are important components that need to function reliably in order to run the plant safely or mitigate the consequences of accidents.[1]

Differing View/Opinion

For the following reasons, I believe that the proposed rule, as currently constructed, will not provide adequate protection of public health and safety and could result in an unsafe condition at nuclear power plant sites.

- The categorization and treatment process are not adequately linked to ensure that changes to risk are maintained small.

- The proposed rule is technically inadequate to provide reasonable confidence that RISC-3 SSCs will be capable of performing their safety functions under design-basis conditions.

- The monitoring, corrective action, and feedback required by the proposed rule is not adequate to ensure that timely adjustments are made to the categorization and treatment processes as necessary to maintain safety.

<u>The categorization and treatment process are not adequately linked to ensure that changes to risk are maintained small.</u>

The categorization process uses long-term average unavailabilities and failure probabilities that are based on steady state assumptions. Other than common cause failures among selected basic events, dependencies among basic events, such as might be introduced by changes to the treatment applied to these SSCs, are generally not modeled. As a result, the importance of certain components or groups of components may not be appropriately categorized. In addition, the treatment portion of the proposed rule is so generally worded and subject to mis-interpretation that licensees could easily establish treatment processes that are ineffective at ensuring that RISC-3 SSCs would be capable of reliably performing their design-basis functions. As a result, licensees that implemented treatment programs, that they believe comply with the proposed rule, could fail to detect degradation that could result in multiple component failures during a single design-basis event.

The proposed rule no longer requires licensees to “characterize the effects of the treatment to be applied to RISC-3 SSCs on SSC capability and performance characteristics under design basis and severe accident conditions.” As such, neither the licensee nor the NRC will be able to make a quantitative assessment of the change in risk associated with the proposed treatment changes. Rather, the proposed rule relies on evaluations (e.g., sensitivity studies) performed by the licensee that assume a certain change in SSC reliability to obtain a sense of what the potential change in risk might be. There is no requirement that the evaluations produce a bounding assessment of the potential change in risk associated with the change in treatment that will be applied to RISC-3 SSCs. While the rule does require “a description of, and basis for acceptability of the evaluations,” there is no standard and very little guidance on what would constitute an acceptable basis (particularly in the areas of fire, seismic, high winds,

and other external events). Changes to treatment practices (such as not performing maintenance on a vendor-recommended schedule) could have a significant impact on SSC reliability such that the evaluations (e.g., sensitivity studies) would not be valid. There is no technical basis for assuming that the factor of 2 to 5 will bound the potential change in reliability or failure rates associated with changes to the treatment of RISC-3 components. There needs to be a process that either ensures that what we are allowing by 50.69 is safe (e.g., by doing either a best estimate or bounding sensitivity studies) or the process should monitor SSC capability/reliability sufficiently to ensure that the unavailabilities are adequately maintained (i.e., ensure that unavailabilities and reliabilities do not exceed the values assumed in the sensitivity studies). In other words, a sensitivity study where the unreliability of all RISC-3 SSCs are increased by a factor of 2 to 5 is only valid if 1) there is data to support the assertion that reduced treatment will not have a significant affect on availability and reliability of these components, or 2) measures are taken to ensure that the failure rate distributions of these SSCs do not shift unexpectedly as a result of the reduced treatment (i.e., by monitoring and corrective action).[2]

Total elimination of regulatory special treatment requirements and reliance on high-level treatment objectives and the licensee's commercial practices would likely result in significant degradation to safety-related equipment that is not directly involved with power production (e.g., standby safety systems) as a result of reduced maintenance, QA, testing, and inspection. Even if the licensee initially established effective maintenance, QA, inspection, testing and surveillance processes for the treatment of these components, economic pressures at some utilities could ultimately result in marginally acceptable or ineffective programs. This degradation would also likely go undetected as a result of being exempt from maintenance rule monitoring, Appendix B, inservice inspection, inservice testing, and regulatory oversight. The potentially widespread degradation of these safety-related components might only manifest itself during a design-basis event. This would be an unacceptable situation (and one which has not been explicitly evaluated by the staff in terms of changes to CDF and LERF).[3]

The proposed rule also no longer requires timely monitoring and adjustment of the categorization or treatment processes to ensure that sensitivity study assumptions remain valid (e.g., provide prompt adjustment of the treatment being applied to the RISC-3 SSC if the monitoring and corrective action programs suggest that the reduced treatment is having an adverse effect of SSC functionality) and thereby ensure acceptable levels of safety are maintained. The proposed rule also no longer requires that significant conditions adverse to quality be evaluated for their applicability to other components (as such, common-cause failures could go uncorrected).

Requiring the use of the ASME risk-informed Code Cases (or an equivalently effective approach developed by the licensee) could be used to provide reasonable confidence that any substantive shift in RISC-3 SSC capability/reliability would be detected and corrected in a timely manner. This approach was presented to the Risk-Informed Licensing Panel (RILP) and Executive Team (ET), but was rejected because it was viewed as a "how" as opposed to a "what."

The proposed rule is technically inadequate to provide reasonable confidence that RISC-3 SSCs will be capable of performing their safety functions under design-basis conditions.

In 2001 and in direct support of the 10 CFR 50.69 rulemaking effort, the Division of Engineering contracted the Idaho National Engineering and Environmental Laboratory to compare the special treatment requirements applied to safety-related components at nuclear power plants to commercial practices applied to non-nuclear components. That study concluded, in part, that commercial practices varied widely and that commercial standards by themselves are not adequate to provide reasonable confidence of functionality. Measures such as using a combination of detailed engineering specifications, plant processes and procedures, and multilevel QA programs that provide for less rigor than required for the full 10 CFR 50, Appendix B, but augmented commercial requirements might be one way to establish reasonable confidence of functionality. The study also concluded that plant processes will have a significant effect on providing reasonable confidence of component functionality, and that the adequacy of the commercial standards and reduced plant processes would have to be evaluated on a plant-by-plant basis. Thus, the construct and content of the proposed rule are not consistent with the conclusions of this study.

Based on the South Texas Project exemption request review (RIP-50 Option 2, proof-of-concept review) such high-level objectives were proven to be ineffective in conveying the staff's expectations relative to the treatment of these SSCs. During the South Texas Project exemption review, the staff and the licensee had extensive discussions and negotiations on each treatment process. For example, with high-level objectives as are currently included in the proposed rule, the licensee stated that bumping a pump or exercising a motor-operated valve would provide them with confidence that the pump or valve would be capable of performing their safety-related functions under design-basis conditions.[4] These approaches were found by the staff to be inadequate in providing reasonable confidence of the components' ability to function under design-basis conditions. The high-level objectives were adjusted based on these discussions and are reflected in the licensee's FSAR (Section 13.7.3) which are subject to specific regulatory controls. Language was included in the STP FSAR to preclude ineffective implementation of their high-level treatment objectives.

The Division of Engineering used the INEEL report (NUREG/CR-6752) and the lessons learned from the South Texas Project exemption request review to identify a minimal set of treatment requirements to be included in the 10 CFR 50.69 rule. Over about a two year period, NRR management (via direction from various management teams and partially in response to stakeholder input on draft versions of the rule) whittled away at this minimal set of treatment requirements (e.g., by voting on alternatives with varying level of detail, by using boundary conditions to define the appropriate content of the rule, by deciding that the proposed rule should only contain high-level treatment requirements that specify what the NRC's expectations are related to RISC-3 SSCs as opposed to specifying how those expectations are to be satisfied, by arguing that the proposed rule is a categorization rule). The process used to develop the proposed rule did not focus on safety and certainly was not efficient and effective. Nevertheless, the staff developed a draft version of the proposed rule which all internal stakeholders found to be acceptable (August 2, 2002, NRC external website version). Then, during the concurrence process, senior management made significant technical and policy adjustments to the proposed rule without providing a technical basis for the changes and without receiving any formal comments from stakeholders. The *Alternative Treatment Requirements* portion of the proposed rule for RISC-3 SSCs is shown below. Rule language that was deleted from the August 2, 2002, NRC website version of the rule, to arrive at the proposed rule, is shown in bold (additions are underscored).

[NOTE: Text in bold is not in the proposed rule.]

(2) *RISC-3 SSCs*. The licensee or applicant shall develop and implement processes to control the design; procurement; inspection, maintenance, testing, and surveillance; and corrective action for RISC-3 SSCs to provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety-related functions under design-basis conditions throughout their service life. **These processes must meet voluntary consensus standards which are generally accepted in industrial practice, and address applicable vendor recommendations and operational experience. The implementation of these processes and the assessment of their effectiveness must be controlled and accomplished through documented procedures and guidelines. The treatment processes must be consistent with the assumptions credited in the categorization process.** The processes must also meet the following requirements, as applicable:

(i) *Design Control*. Design functional requirements and bases for RISC-3 SSCs must be maintained and controlled**, including selection of suitable materials, methods, and standards; verification of design adequacy; control of installation and post-installation testing; and control of design changes**. RISC-3 SSCs must **have a documented basis to demonstrate that they are** be capable of performing their safety-related functions including design requirements for environmental conditions (i.e., temperature and pressure, humidity, chemical effects, radiation, and submergence) and effects (i.e.,aging and synergisms); and seismic conditions (design load combinations of normal and accident conditions with earthquake motions). **Replacements for ASME Class 2 and Class 3 SSCs or parts must meet either: (1) the requirements of the ASME *Boiler & Pressure Vessel (BPV) Code*; or (2) the technical and administrative requirements, in their entirety, of a voluntary consensus standard that is generally accepted in industrial practice applicable to replacement. ASME Class 2 and Class 3 SSCs and parts shall meet the fracture toughness requirements of the SSC or part being replaced.**

(ii) *Procurement*. Procured RISC-3 SSCs must satisfy their design requirements. **Upon receipt, the licensee shall verify that the item received is the item that was ordered.**

(iii) *Maintenance, Inspection, Testing, and Surveillance*. Periodic maintenance, inspection, testing, and surveillance activities must be established and conducted using prescribed acceptance criteria, and their results evaluated to determine that RISC-3 SSCs will remain capable of performing their safety-related functions under design-basis conditions until the next scheduled activity.

(iv) *Corrective Action*. Conditions that could prevent a RISC-3 SSC from performing its safety-related functions under design-basis conditions must be identified, documented, and corrected in a timely manner. **In the case of significant conditions adverse to quality, measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition.**

Management's position is that, as a matter of policy, such high-level treatment requirements [i.e., without the bold language] provides the appropriate level of regulatory control, given the robustness of the categorization process and the low safety significance of the components. Management states that reliance on such high-level treatment requirements [i.e., without the bold language] is consistent with Commission expectations and that including the bolded language would be inconsistent with the Commission's expectation. However, it is not clear why this language has been deleted from the proposed rule when the accompanying Statements of Consideration clearly states that licensees will be expected to do these things.

The text which was deleted from the proposed rule is necessary to provide reasonable regulatory confidence that the RISC-3 SSCs will remain functional. For example, deleting the requirement that licensees comply with voluntary consensus standards removes the technical basis for asserting that the proposed rule will provide reasonable confidence that RISC-3 SSCs will be capable of performing their safety functions under design-basis conditions. Ad hoc treatment of RISC-3 SSCs by licensees fails to take advantage of the technical expertise of industry standard setting groups, is inconsistent with the National Technology Transfer and Advancement Act of 1995, Public Law 104-113), and could result in inadequate or ineffective treatment of RISC-3 SSCs. In many cases, these consensus standards already explicitly address how to treat low safety significant components. Further, deletion of the requirement to consider vendor recommendations and industry operating experience could result in use of outdated technical information, repetition of poor practices of the past, and common-cause problems that would affect multiple SSC functionality. It is not clear why this requirement was deleted from the proposed rule when the Statement of Considerations in support of the proposed rule clearly states (on page 75) that "the proposed rule permits, but does not require, use of the Code Cases for purposes of meeting rule requirements," and "the Commission expects licensees will utilize the ASME Code Cases as part of their implementation of §50.69." However, nothing in the rule would prompt licensees to utilize the Code Cases and there will be no regulatory guidance to steer licensees in this direction. If the Commission's expectation is that licensees use the Code Cases then the deleted language (i.e., these processes must meet voluntary consensus standards which are generally accepted in industrial practice) should be included in the rule.

As a second example, documented procedures and guidelines are needed for RISC-3 treatment processes and assessments of their effectiveness to provide reasonable confidence in the functionality of RISC-3 SSCs for initial implementation and follow-up activities. Allowing treatment processes to be undocumented will fail to provide reasonable confidence that activities related to RISC-3 SSCs will be implemented adequately. Absence of a requirement to control assessments of the effectiveness of the licensee's treatment processes will result in the inability to rely on the licensee's internal processes to manage and audit the treatment processes.

As a final example, the requirement that measures be taken to assure that the cause of significant conditions adverse to quality be determined and corrective action taken to preclude repetition is also necessary to provide reasonable confidence that RISC-3 SSCs will be capable of performing their safety functions under design-basis conditions. The licensee's treatment processes must guard against widespread common cause failures. Experience indicates the changes to treatment (e.g., maintenance, test, and inspection practices) can have a significant and widespread effect on component capability and reliability and could invalidate the safety analysis performed to justify the changes. The proposed rule only requires specific failed SSC to be repaired. The proposed rule does not contain a requirement for potential common-cause problems to be evaluated and corrected. Common-cause problems that extend across system boundaries can invalidate the categorization process and result in inadequate protection of public health and safety. It is not clear why this requirement was deleted from the proposed rule when the Statement of Considerations clearly states that "effective implementation of the corrective action process would include timely response to information from plant SSCs, overall plant operations, and industry generic activities that might reveal performance concerns for RISC-3 SSCs on both an individual and common-cause basis".

Reliance on the very high-level treatment objectives, as contained in the proposed rule, will not provide reasonable confidence that the RISC-3 SSCs will remain functional. As learned from the RIP-50 Option 2 proof-of-concept exemption request review, high-level requirements alone are inadequate to provide reasonable confidence that licensees will implement sufficient treatment such that RISC-3 SSCs will perform their safety function under design-basis conditions. Moreover, reliance on very high-level treatment objectives will not ensure that degradation that could significantly affect the ability of groups of RISC-3 SSCs to perform their safety function reliably will be detected and corrected in a timely manner.

<u>The monitoring, corrective action, and feedback required by the proposed rule is not adequate to ensure that timely adjustments are made to the categorization and treatment processes as necessary to maintain safety.</u>

The proposed rule should describe (i.e., require) a treatment process that will provide reasonable confidence in the functionality of the RISC-3 SSCs. As currently constructed, the proposed rule relies too heavily on the categorization process. It is overly risk-based and fails to embrace one of the key safety principles identified in RG 1.174, that is, "The impact of the proposed change should be monitored using performance measurement strategies." RG 1.174 clearly states that "[t]he staff expects licensees to propose monitoring programs that include a means to adequately track the performance of equipment that, when degraded, can affect the conclusions of the licensee's engineering evaluation and integrated decisionmaking that supports the change to the LB." The proposed Option 2 rule should propose monitoring that is consistent with this guidance or there should be a technical basis for why such monitoring is no longer considered necessary.

As stated earlier, the staff developed a draft version of the proposed rule which all internal stakeholders found to be acceptable (August 2, 2002, NRC website version). Then, during the concurrence process, senior management made significant adjustments to the proposed rule without providing a technical basis for the changes and without receiving any formal comments from stakeholders. The *Feedback and Process Adjustment* portion of the proposed rule is shown below. Rule language that was deleted from the August 2, 2002, NRC website version of the rule, to arrive at the proposed rule, is shown in bold (additions are underscored).

[NOTE: Text in bold is not in the proposed rule.]

Feedback and process adjustment.

(1) *RISC-1, RISC-2, RISC-3 and RISC-4 SSCs*. In a timely manner and no longer than every 36 months, the licensee shall review changes to the plant, operational practices, applicable industry operational experience, and, as appropriate, update the PRA and SSC categorization.

(2) *RISC-1 and RISC-2 SSCs*. The licensee shall monitor the performance of RISC-1 and RISC-2 SSCs and **in a timely manner and no later than every 36 months, perform an evaluation to assess whether the performance is consistent with the performance credited in the categorization process. Based upon that evaluation, the licensee shall** make adjustments as necessary to either the categorization or treatment processes **to provide continued support for the assumptions of the categorization process and its results**.

(3) *RISC-3 SSCs*. The licensee shall consider **performance** data collected in § 50.69(d)(2)(iii) for RISC-3 SSCs to determine **if the performance is consistent with performance credited in the categorization process, and** whether there are any adverse changes in performance **are due to changes in treatment applied to that SSC. In a timely manner and no later than every 36 months, the licensee shall make** such that the SSC unreliability values approach or exceed the values used in the evaluations conducted to satisfy § 50.69 (c)(1)(iv) and shall adjustments as necessary to either the categorization or treatment processes **to provide continued support for the assumptions of the categorization process and its results**.

My concern with the *Feedback and process adjustment* portion of the proposed rule is twofold. First, it does not require that the categorization process assumptions and treatment applied to RISC-3 SSCs be maintained consistent (as is required for the RISC-1 and RISC-2 SSCs). Second, it does not require timely adjustment to the treatment, or categorization process, if RISC-3 performance degrades significantly.

Recognizing that data does not currently exist to predict the effect of reduced treatment on RISC-3 SSC availability and reliability, it is particularly important to establish a process that maintains the treatment applied to the RISC-3 SSCs consistent with the categorization process assumptions. The overall process should require timely evaluation of performance problems that occur with RISC-3 SSCs, particularly problems that could pose a common cause concern, and require prompt adjustments to the treatment being applied to the RISC-3 SSCs or re-evaluation as part of the categorization process. In this way, the change in risk can be maintained acceptably small while data is obtained on the effects of reduced treatment on RISC-3 availability and reliability. This linkage between categorization and treatment needs to be unambiguously clear in the rule. The categorization portion of the proposed rule at (c)(1)(iv) currently states:

> Provide reasonable confidence that for SSCs categorized as RISC-3, sufficient safety margins are maintained and that any potential increases in core damage frequency (CDF) and large early release frequency (LERF) resulting from changes in treatment permitted by implementation of § 50.69(b)(1) and § 50.69(d)(2) are small [where § 50.69(b)(1) lists the rules that RISC-3 SSCs are being exempted from and § 50.69(d)(2) lists the alternate treatment requirements for RISC-3 SSCs].

This requirement does not clearly require that the categorization process assumptions and treatment applied to RISC-3 SSCs be maintained consistent. The proposed rule requirement above also does not require timely adjustments to the treatment being applied to the RISC-3 SSCs or re-evaluation as part of the categorization process. As a result, this portion of the proposed rule does not provide reasonable confidence that risk associated with the reduced treatment will be maintained acceptably small and does not provide adequate feedback to ensure RISC-3 functionality.

In addition to the above safety concerns, I have the following process concerns with the proposed rule and the way it was developed.

The proposed rule is inconsistent with the Commission's PRA Policy Statement and with the Commission-approved description of Option 2.

The Commission's PRA Policy Statement states that "use of PRA technology should be increased in all regulatory matters to the extent supported by state-of-the-art in PRA methods and data." There is insufficient data regarding the effect of reduced treatment on RISC-3 reliability to assess the change in CDF and LERF associated with the proposed rule. While sensitivity studies can be used to assess the potential change in CDF and LERF, the rule needs to require that any assumptions made in those sensitivity studies remain valid. This provision of the draft rule (published on the NRC's website) was deleted without any official public comment from stakeholders. SECY-99-256 indicates that "RISC-3 SSCs will need to receive sufficient regulatory treatment such that these SSCs are still expected to meet functional requirements, albeit at a reduced level of assurance." As mentioned above, the proposed rule does not provide reasonable confidence that the RISC-3 SSCs will remain functional.

The proposed rule is not responsive to public comments received from ASME and exceeds some suggestions provided by NEI.

In its letter dated June 17, 2002, ASME agreed with the provision in the draft versions of the rule to exempt licensees that implement 50.69 from the requirements of 50.55a provided a framework is developed to ensure that the ASME's risk-informed Code Cases and Codes & Standards are used. In its letter dated May 15, 2002, NEI did not object to requirements regarding use of national codes and standards, specific design control aspects, and procurement receipt verification. At a public meeting on June 18, 2002, NEI stated that it did not have a problem with requiring that applicable voluntary consensus standards be used. The provision of the draft rule (published on the NRC's website) which would require that the treatment processes meet voluntary consensus standards, as well as other provisions in the draft rule, were deleted without any official public comment from stakeholders.

The established process for developing the proposed rule was not followed.

Significant technical and policy changes were made to the proposed rule package during the concurrence process without consulting with the technical staff, without providing a technical basis, without discussing the changes with the teams that were involved with developing the rule (e.g., RIP-50 Core Team, Risk Management Team, Risk-Informed Licensing Panel), and without receipt of official public comments. As a result of hastily making these changes to the proposed rule, there are significant inconsistencies between the proposed rule and associated Statement of Considerations. Staff expectations and requirements described in the Statement of Considerations are often not supported by language in the proposed rule.

For example, the Statement of Considerations states (page 80) that "Licensees will have to establish appropriate performance-based SSC treatment processes to maintain the validity of the categorization process and its assumptions." Page 101 of the Statement of Considerations discusses "developing and maintaining a technical basis for concluding that SSC performance is consistent with the categorization assumptions and with those evaluations performed to show that there is no more than a small increase in risk associated with implementation of § 50.69." The Statement of Considerations also states (page 101) that "changing levels of treatment on several similar components that might be sensitive to CCF potential would require consideration as to whether the planned monitoring and corrective action program, or other aspects of treatment, would be effective in sufficiently minimizing CCF potential such that the sensitivity studies remain bounding." Similarly, the Statement of Considerations (page 108) indicates that "the categorization process may include specific reliability assumptions for plant SSCs in performing their intended functions. Therefore, when establishing the performance-based treatment process for RISC-3 SSCs, the licensee must take these assumptions into account. It is important to obtain sufficient information on SSC performance to allow the assumptions and results of the categorization process to remain valid." However, the development and maintenance of this linkage between the categorization and treatment processes is not required by the proposed rule and cannot be reasonably be read into the rule.

In addition, the Statement of Considerations identifies expectations related to the categorization process that are not supported by language in the proposed rule. For example (page 96):

- It is expected that a sufficiently robust categorization process would result in the reactor coolant pressure boundary being categorized as RISC-1.

- It is expected for PWRs that a sufficiently robust categorization process would categorize high energy ASME Section III Class 2 piping of the main steam and feedwater systems as RISC-1.

- It is expected that a sufficiently robust categorization process would result in fission product barriers (e.g., the containment shell or liner) being categorized as RISC-1.

The Statement of Considerations also identifies expectations related to the treatment process that are not supported by language in the proposed rule. For example:

- The Commission expects that related standards (such as ASME Code Cases N-658 and N-660 on SSC categorization and treatment for purposes of repair and replacement) be

used in conjunction with each other as intended by the accredited standards writing body (page 109).

- The licensee's design control process would be expected to specify appropriate quality standards; select suitable materials, parts, and equipment; control design interfaces; coordinate participation of design organizations; verify design adequacy; and control design changes (page 112).

- The Commission also expects licensees to control special processes associated with installation, such as welding, to provide reasonable confidence in the design-basis capability of RISC-3 SSCs (page 114).

- For a RISC-3 SSC in service beyond its design life, the Commission expects licensees to have a documented technical basis to determine that the SSC will remain capable of performing its safety-related function (page 117).

These types of expectation should be reasonably linked to specific language in the proposed rule. Furthermore, I believe that turning these expectations into requirements of the rule would not be inconsistent with the Commission's expectations as articulated in the Staff Requirements Memoranda (SRMs) in response to SECY-98-300, SECY-99-256, and SECY-00-0194 (SRMs dated 6/8/99, 1/31/00, and 11/9/00, respectively).

As a final note, the strategy of publishing *Additional potential requirements for public comment* (Section VI of the Statement of Considerations) containing the treatment portion of the August 2, 2002, NRC website version of the rule for public comment, in addition to the less prescriptive proposed rule language, will probably not yield any fruitful responses and should be abandoned.

Conclusion

The proposed rule, as it is currently constructed, does not provide reasonable confidence that the change in risk associated with implementation of the rule will be maintained acceptably small. The proposed rule, as it is currently constructed, also does not provide sufficient regulatory assurance that RISC-3 SSCs (most of the safety-related equipment at the plant) will function reliability. The proposed rule simply requires that licensee establish processes to ensure that the RISC-3 SSCs will perform their safety functions under design-basis conditions. Finally, because of the construct of the current Reactor Oversight Process, the NRC won't periodically check to see if the licensee treatment processes for this "low-risk" equipment are effective. Consequently, I believe that the proposed rule, as currently constructed, will not provide adequate protection of public health and safety and could result in an unsafe condition at nuclear power plant sites.

Recommendations

The proposed rule should describe a process that considers the potential effects of reduced treatment on SSC reliability and availability both in categorizing components and in assessing the potential change in risk associated with implementing the rule. The proposed rule should describe a process (i.e., monitoring, corrective action, and feedback) that ensures PRA

assumptions are maintained or that adjusts the treatment being applied to the RISC-3 SSCs as appropriate.

In order to demonstrate that the potential changes in CDF and LERF from the reduced treatment being applied to RISC-3 SSCs are small, the licensee should either 1) determine the effects of reduced treatment to be applied to RISC-3 SSCs on their unavailability and reliability, 2) perform a bounding analysis, or 3) perform sensitivity studies that reasonably assess potential changes that could occur and then monitor RISC-3 performance against the assumptions made in the sensitivity studies. Whichever option is chosen, the licensee should have a technical basis for any assumptions made or the licensee should establish a process that ensures that the assumptions are not inadvertently invalidated.

The proposed rule should make use the ASME's Risk-Informed Code Cases, as endorsed by the NRC staff, or an approach developed by the licensee that provides an equivalent level of effectiveness, as an acceptable method for meeting the high-level objectives of the rule (i.e, maintaining the ability of RISC-3 SSCs to perform their safety-related functions under design-basis conditions). These Code Cases were developed by technical experts as part of a national consensus process. They will address all the major areas in the Code (e.g., ISI, IST, repair and replacement). The Risk-Informed Code Cases define appropriate, generally performance-based test and inspection strategies specifically for low safety significant components. Use of the ASME risk-informed Code Cases would provide reasonable confidence that RISC-3 SSCs would remain functional and would result in a more consistent approach towards the treatment of the RISC-3 SSCs. Such monitoring, if adequately coupled to the licensee's corrective action program, could also be used as a technical basis for asserting that sensitivity studies adequately bound potential increases in CDF and LERF associated with reduced treatment.

Referencing the ASME Code Cases, as endorsed by the NRC staff, will demonstrate that the Agency has a preeminent concern for maintaining public health and safety and will, at the same time, significantly reduce unnecessary regulatory burden (e.g., consistent with procurement of RISC-3 SSCs to commercial standards). It will also preclude any appearance, to the public or the Congress, of coziness with the regulated nuclear industry by working through the ASME and a national consensus process. Use of the ASME Code Cases, as endorsed by the NRC Staff, would also be consistent with the National Technology Transfer and Advancement Act of 1995.

Rather than relinquish specific regulatory controls for over approximately 75% of the safety-related equipment all at one time (and without having specified our expectations regarding how to meet the high-level objectives identified in the proposed rule), I believe it would be more prudent to significantly reduce the regulatory treatment to be applied to the RISC-3 SSCs by referencing the ASME risk-informed Code Cases as endorsed by the NRC. This would allow licensees to gain experience with the reduced maintenance, testing, inspection, and surveillance strategies and allow both licensees and the NRC to get a better understanding of the effect of reduced treatment on component availability and reliability. As experience is gained applying 10 CFR 50.69, the staff can always revisit whether certain categorization or treatment requirements in the rule are necessary.

The aforementioned concerns and recommendations can be ameliorated, in large part, by issuing the August 2, 2002, NRC website version of the rule (as published on the NRC external website) as the proposed rule.

cc: D. Terao
E. Imbro
W. Dean
R. Barrett

ADAMS ACCESSION NUMBER: ML022690452

Endnotes:

1. Some NRC staff and managers have recently argued that the categorization process proposed under Option 2 is more robust than that which was approved during the South Texas Project exemption review and would result in far fewer, and less safety significant, components being categorized as having low safety significance. However, the proposed rule neither defines nor requires a robust PRA. The categorization requirements in the proposed rule are also written at a very high level and do not ensure that only very insignificant components get categorized as RISC-3. The examples of robustness that have been mentioned are contained in draft regulatory guide DG-1121, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance."

2. While a study conducted by the South Texas Project licensee asserted that non-safety-related failure rates were not appreciably greater than corresponding safety-related failure rates for similar component types, the study was flawed for the following reasons.

- Failure data in NPRDS and MRRI is generally obtained during normal plant operating conditions and may not provide an indication of how the equipment will function under accident conditions.

- There was generally more safety-related equipment experience reported in the databases (because of reporting requirements) than for corresponding types of non-safety-related equipment. The reporting of non-safety-related failure data into NPRDS was voluntary and licensee dependent. As acknowledged in the report, there is incomplete data reporting in NPRDS and MRRI raw data for all component engineering and failure records. As a result, the non-safety-related failure frequencies will tend to be underestimated.

- Counting functional or operational failures over calender hours of plant operation does not give a reasonable estimate of a component's availability/unavailability or a component's reliability if called upon to function under design basis conditions.

- Detailed calculation of demand-based and run-time based failure "rates" similar to those applied in the probabilistic risk assessment (PRA) was not possible within the NPRDS database, because detailed failure mode and demand exposure (or success) data was not included therein. For both demand and run failure rate calculations, most component success or total "exposure" data (i.e., total demands and total run time) values in the MRRI database are estimated, not actually recorded like failure events. The estimates for the demand-based and run-time based failure "rates" assume that safety-related and non-safety-related components have similar demand profiles and run-time profiles. The basis for this assumption needs to be explained.

- Only functional or operational failures were considered in the analysis. There was no indication that other component records were evaluated to determine whether deficiencies identified in them would have prevented the component from functioning under design-basis-accident conditions.

- Only NPRDS safety class S (safety-related equipment) and safety class N (non-safety-related equipment) data was considered in the analysis. Safety class Z (other) was omitted from the analysis.

3. A more meaningful sensitivity study (than varying the unavailabilities of all RISC-3 SSCs by a factor of 2 to 5) might be to significantly reduce, or set to 1, the unavailabilities of selected RISC-3 SSCs to see the potential effect on CDF and LERF. It is noteworthy that modeling of common cause failures typically would not go across system boundaries. Inasmuch as, reducing the treatment applied to a group of components can both introduce common cause failure mechanisms (e.g., test or maintenance errors) and eliminate the defensive strategies against proximate causes (e.g., design controls, use of qualified equipment, testing and preventive maintenance programs, procedural review, personnel training, quality control) it is particularly important to either understand (i.e., up front) the effects of reduced treatment on common cause failure mechanisms or monitor for potentially more widespread common cause concerns. While increasing the failure rates by a factor of 2 to 5 also increases the common-cause failure contribution to the overall system unavailability by a factor of 2 to 5, it generally does not address inter-system common cause concerns and it is not mathematically correct in that parametric multipliers are neither known nor estimated.

4. The Commission previously concluded in NRC Generic Letter 89-10, “Safety-Related Motor-Operated Valve Testing and Surveillance,” dated June 28, 1989, and again in the Supplementary Information in support of the September 22, 1999, revision to 10 CFR 50.55a (64 FR 51370) that the quarterly stroke-time testing requirements for MOVs in the Code are not sufficient to provide assurance of MOV operability under design-basis conditions. Therefore, elimination of a licensee’s commitment to conduct periodic diagnostic testing (on an interval as long as once every 10 years based on valve performance) in conjunction with more frequent exercise testing [i.e., once a year or every refueling outage (whichever is longer)], in lieu of the quarterly stroke-time testing, would be unsafe.

September 26, 2002

MEMORANDUM TO: Samuel J. Collins, Director
Office of Nuclear Reactor Regulation

FROM: John R. Fair, Senior Mechanical Engineer ***/RA/***
Mechanical and Civil Engineering Branch
Division of Engineering
Office of Nuclear Reactor Regulation

SUBJECT: DIFFERING PROFESSIONAL VIEW CONCERNING THE PROPOSED 10 CFR 50.69 RULEMAKING

The purpose of this memorandum is to document my differing professional view concerning the proposed rulemaking to add new section 10 CFR 50.69, "Risk Informed Categorization and Treatment of Structures, Systems, and Components." My specific concern is that the treatment requirements specified for RISC-3 SSCs are not sufficient to provide reasonable assurance of adequate protection of public health and safety.

The staff in NRR has spent over two years developing the 50.69 rule language. This effort included numerous internal staff meetings, review by internal oversight groups, and public meetings with external stakeholders. This effort resulted in the July, 31, 2002, version of the rule published on the NRC web site (posted on August 2). The July 31 version of the rule represented the balance of categorization and treatment requirements necessary to achieve a staff consensus to go forward with the proposed rulemaking. The Division of Regulatory Improvement Programs significantly altered the July 31 version of the rule without any input from the technical reviewers that were involved in the development of the rule for the past two years. Critical portions of the treatment process were eliminated based on the nebulous assertion that the rule language contained too much detail. The accompanying statement of considerations (SOC) indicates that the Commission expects licensees and applicants to satisfy many of the treatment provisions that were eliminated from the July 31 rule language. The current rule language is not consistent with many of the SOC expectations. As discussed in the ensuing paragraphs, portions of the July 31 rule language were eliminated without a valid technical justification.

The following language was deleted from the general treatment requirements for RISC-3 SSCs specified in the July 31 version of 50.69(d)(2):

> *These processes must meet voluntary consensus standards which are generally accepted in industrial practice, and address applicable vendor recommendations and operational experience. The implementation of these processes and the assessment of their effectiveness must be controlled and accomplished through documented procedures and guidelines. The treatment processes must be consistent with the assumptions credited in the categorization process.*

Section III.3.2 of the SOC contains the statement: "Thus, collectively, RISC-3 SSCs can be safety significant and it is important to maintain their design basis functional capability." It is important to recognize that, although on an individual basis RISC-3 SSCs may have low risk significance, collectively RISC-3 SSCs are safety significant. The failure of even a small number of these RISC-3 SSCs could lead to serious safety consequences. Therefore, in order for the staff to conclude that 50.69 provides reasonable assurance of adequate protection of public health and safety, the staff must conclude that the RISC-3 treatment requirements provide an adequate framework for assuring that RISC-3 SSCs maintain their design basis functionality. As stated in Section V.4.4 of the SOC, "It is necessary for a licensee to consider the impact that a change in treatment (as a result of removal of special treatment requirements) might have on the ability of the SSC to perform its design basis function and on the reliability of SSCs." The SOC further concedes that this assessment may be either quantitative or qualitative. This is a weakness in the categorization process. A key cornerstone of the robust categorization process, the sensitivity study, may hinge on individual judgement. Safety-related SSCs are assumed to be highly reliable. A change in unavailability by a factor of 2 to 5, such as recommended in the NEI categorization guidelines (NEI 00-04) for the sensitivity study, still requires that the SSCs remain highly reliable. Monitoring normal operational SSC performance will not provide reliability estimates of SSC performance during design basis events. In order to have reasonable confidence that high reliability of SSCs is achieved for all design basis conditions, the RISC-3 treatment processes must meet standards that are generally accepted in industrial practice along with applicable vendor recommendations, and must be accomplished using controlled procedures. It is difficult to understand why these general requirements were considered too detailed for the rule language. Consensus standards and vendor recommendations are developed considering past performance of SSCs. The consensus standards and vendor recommendations contain essential criteria that is necessary to provide confidence in the functionality of SSCs. If licensees and applicants don't use available consensus standards and don't even follow vendor recommendations, the staff will not have a basis to assess reliability assumptions used in the categorization process.

The following bracketed language was deleted from the design control requirements specified in the July 31 version of 50.69(d)(2)(i):

> *Design functional requirements and bases for RISC-3 SSCs must be maintained and controlled ["including selection of suitable materials, methods, and standards; verification of design adequacy; control of installation and post-installation testing; and control of design changes"]. RISC-3 SSCs must be ["have a documented basis to demonstrate that they are"] capable of performing their safety-related functions...*

Post-installation testing is an essential step in establishing the functionality of newly installed SSCs. Section V.5.2.1 of the SOC contains the statement: "Licensees would be expected to perform sufficient post-installation testing to verify that the installed SSC is operating within expected parameters and is capable of performing its safety functions under design-basis conditions." It is not clear why the requirement for post-installation testing was deleted from the rule language if licensees are expected to perform post-installation testing.

The current rule language does not require licensees and applicants to have any documentation to show that design requirements have been met. This is a significant deficiency in the current rule language. Without documentation, there is no assurance that

SSCs meet their design requirements and, consequently, no assurance that design basis functionality has been maintained. Maintaining documentation to show that design requirements have been met is a relatively simple common sense requirement. It is not clear why this requirement was considered overly prescriptive and removed from the rule language.

The following additional language was removed from the design control provisions specified in the July 31 version of 50.69(d)(2)(i):

> *"Replacements for ASME Class 2 and Class 3 SSCs and parts must meet either: (1) the requirements of the ASME Boiler & Pressure Vessel (BPV) Code; or (2) the technical and administrative requirements, in their entirety, of a voluntary consensus standard that is generally accepted in industrial practice applicable to replacement. ASME Class 2 and Class 3 SSCs and parts shall meet the fracture toughness requirements of the SSC or part being replaced."*

Proposed 50.69(b)(1)(iv) allows licensees to replace ASME SSCs with non-ASME SSCs. This constitutes a change in the design of these components since the ASME Code contains design requirements. As a consequence, it is necessary to establish some criteria for the design of these SSCs. Section III.3.2 of the SOC contains the statement, "For the specific case of repair and replacement of ASME Class 2 and Class 3 SSCs, the Commission concludes that it would be acceptable to allow these SSCs to meet a voluntary consensus standard that is generally accepted in industrial practice..." However, the current rule language does not require these SSCs to meet any standard. The July 31 rule language is necessary to achieve the stated objective in the SOC. Section V.5.2.1 of the SOC also contains the statement, "Another example is a requirement for fracture toughness of particular materials that is part of a licensee's design requirements; such a requirement would continue to apply when repair and replacement of affected components is undertaken." However, the fracture toughness requirements are specified in the ASME Code. If a licensee does not use the ASME Code for replacement SSCs, then fracture toughness requirements will be lost. That is the reason the fracture toughness was addressed in the July 31 rule language. If SSCs do not possess adequate fracture toughness, then multiple brittle failures could occur when the SSCs are challenged by a design basis event such as an earthquake.

The following language was removed from the procurement provisions specified in the July 31 version of 50.69(d)(2)(ii):

> *"Upon receipt, the licensee shall verify that the item received is the item that was ordered."*

The purpose of the rule language is to assure that licensees and applicants maintain some control over procured items. Lack of procurement control could result in the installation of SSCs that are not capable of performing their design basis function. Section V.5.2.2 of the SOC contains the statement: "In addition to appropriately specifying the procurement of the desired component, the licensee/applicant would also be expected to conduct activities upon receipt to confirm that the received component is what was ordered." It is not clear why the requirement was considered too prescriptive for the rule language if the Commission expects of licensees and applicants to confirm that a received item is what was ordered.

The following language was removed from the corrective action provisions specified in the July 31 version of 50.69(d)(2)(iv):

> *"In the case of significant conditions adverse to quality, measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition."*

Without this requirement a licensee or applicant would only have to fix a deficiency without having to determine whether the deficiency has any generic implications. This could lead to the failure to detect multiple SSCs that are not functional due to a generic deficiency. Section V.5.2.4 of the SOC contains the statement: "For example, effective implementation of the corrective action process would include timely response to information from plant SSCs, overall plant operations, and industry generic activities that might reveal performance concerns for RISC-3 SSCs on both an individual and common-cause basis." The current rule language in not consistent with that statement. It is not clear why this provision was removed from the rule language.

In summary, the provisions of the July 31 rule language that were deleted contained high level requirements the technical staff considered necessary to provide reasonable confidence in the functionality of RISC-3 SSCs. The requirements in the current rule language are not sufficient for the staff to conclude that 50.69 provides reasonable assurance of adequate protection of public health and safety.

cc: R. Barrett
E. Imbro

ADAMS ACCESSION NUMBER: ML022690398

September 26, 2002

MEMORANDUM TO: Samuel J. Collins, Director
Office of Nuclear Reactor Regulation

FROM: Thomas G. Scarbrough ***/RA/***
Mechanical and Civil Engineering Branch
Division of Engineering
Office of Nuclear Reactor Regulation

SUBJECT: DIFFERING PROFESSIONAL VIEW REGARDING PROPOSED 10 CFR 50.69, "RISK-INFORMED CATEGORIZATION AND TREATMENT OF STRUCTURES, SYSTEMS, AND COMPONENTS FOR NUCLEAR POWER REACTORS"

For many years, NRC staff members in the NRR Division of Engineering (DE) have been reviewing and approving the application of risk insights in licensee programs at nuclear power plants through risk-informed inspection and testing programs. I have participated in these activities, including review of the application of risk insights in motor-operated valve (MOV) testing programs and assisting in the development of guidelines for the implementation of risk-informed testing programs at nuclear plants. Recently, I participated as a principal DE reviewer for the request by the South Texas Project for exemption from multiple special treatment requirements through the application of risk insights. Throughout this time, I and other members of the DE staff have supported the application of risk insights in NRC activities, and encouraged the implementation of risk-informed inspection and testing programs by nuclear plant licensees.

Over the last two years, I have participated as a principal DE reviewer for Option 2 of the NRC staff initiative to incorporate risk insights into the regulations. In this assignment, I have applied knowledge obtained from my experience during NRC activities to evaluate licensee programs to verify the design-basis capability of safety-related MOVs, review and acceptance of risk-informed and deterministic inservice testing programs established and implemented at nuclear plants, and participation in ASME code and standard activities including development of provisions for risk-informed component testing programs. Although the goal of the Option 2 effort is strongly supported by all internal and external stakeholders, significant differences exist regarding the interpretation of the Commission's directives for the Option 2 effort, the safety function of plant structures, systems, and components (SSCs) ranked as having low safety significance by the categorization process, and the implementation of high-level treatment requirements for low safety significant SSCs.

The NRC staff expended considerable resources to prepare proposed 10 CFR 50.69, "Risk-Informed Categorization and Treatment of Structures, Systems, and Components for Nuclear Power Reactors," to satisfy the directives in the Commission papers describing the Option 2 effort. For example, the staff provided an opportunity for advance public comment on drafts of the rule language per Commission direction. The staff also conducted several public meetings to discuss draft rule language and to consider comments submitted by stakeholders.

On July 31, 2002, the staff prepared a draft rule for Commission review that specified high-level requirements to provide sufficient regulatory treatment for plant SSCs consistent with the Commission papers describing the Option 2 effort. However, the 50.69 rulemaking package was significantly modified during the concurrence process. Based on my experience in component engineering and lessons learned from the Option 2 proof-of-concept effort, I consider the rulemaking package for proposed 10 CFR 50.69 submitted for Commission approval to be insufficient to maintain adequate protection of the public health and safety during operation of nuclear power plants implementing the rule. Therefore, I am submitting this Differing Professional View (DPV) regarding the rulemaking package for proposed 10 CFR 50.69.

As discussed in detail in the attachment to this memorandum, it is my opinion that the rulemaking package for proposed 10 CFR 50.69:

- does not specify requirements necessary to provide reasonable confidence in the functionality of safety-related structures, systems, and components categorized as low risk (RISC-3 SSCs) by failing to recognize the importance of RISC-3 SSCs on a multiple SSC basis, to address the potential for common-cause interactions in the treatment process, and to incorporate lessons learned from NRC plant-specific and generic evaluations of nuclear power plant programs;

- is inconsistent with the Commission's Probabilistic Risk Assessment (PRA) Policy Statement; the Commission's directives for implementing Option 2 of the NRC initiative to risk-inform the regulations; and the Commission's White Paper on Risk-Informed and Performance-Based Regulation;

- does not provide a balanced discussion in the accompanying Commission paper of this first-of-a-kind regulation that will eliminate most special treatment requirements for most safety-related SSCs in operating and future nuclear power plants;

- provides a Statement of Considerations that is inconsistent with the proposed rule, and is misleading in its presentation of the proposed requirements; and

- fails to resolve safety concerns regarding the proposed rule in a sufficient technical manner.

If 10 CFR 50.69 is issued as proposed, I believe that treatment programs at some nuclear plants that implement the rule will be insufficient to maintain the reliability of SSCs to perform their safety functions assumed in the categorization process. These insufficient treatment programs can result in the unavailability of multiple SSCs to perform their safety functions under design-basis conditions. The unavailability of multiple SSCs to perform their safety functions might not be identified prior to a plant event, and increase the severity of the event or interfere with the licensee's ability to mitigate the event. If unacceptable SSC performance is identified, the absence of documentation allowed by the rule will increase the difficulty for regulatory and licensee staff to determine the extent of functionality concerns to other plant SSCs and the significance of the issue related to public health and safety.

I will be pleased to discuss my safety concerns with the proposed 50.69 rulemaking package.

Attachment: As stated

SAFETY CONCERNS WITH
PROPOSED 50.69 RULEMAKING PACKAGE

1. The proposed 50.69 rule does not specify requirements necessary to provide reasonable confidence in the functionality of safety-related structures, systems, and components categorized as low risk (RISC-3 SSCs) by failing to recognize the importance of RISC-3 SSCs on a multiple SSC basis, to address the potential for common-cause interactions in the treatment process, and to incorporate lessons learned from NRC plant-specific and generic evaluations of nuclear power plant programs.

Proposed 50.69 Rule

The proposed 50.69 rule (as of September 25, 2002) provides a voluntary approach for nuclear power plant licensees to categorize SSCs according to their safety significance and then to establish treatment processes for the SSCs based on their risk category. The proposed rule identifies safety-related SSCs of high safety significance as RISC-1, nonsafety-related SSCs of high safety significance as RISC-2, safety-related SSCs of low safety significance as RISC-3, and nonsafety-related SSCs of low safety significance as RISC-4. The proposed rule would provide for review and approval of the categorization process for each licensee that submitted a license amendment request to implement 10 CFR 50.69. The NRC staff plans to review and endorse guidelines prepared by the Nuclear Energy Institute (NEI) for the categorization of SSCs. The staff also plans to conduct inspections of the categorization process established by licensees implementing the rule.

In implementing 10 CFR 50.69, the licensee would establish treatment processes for individual SSCs based on their safety significance categorization. For RISC-1 and 2 SSCs, the licensee will be required to maintain current regulatory requirements and to adjust treatment to be consistent with credit assumed for those SSCs in the categorization process. For RISC-3 SSCs, the proposed rule would specify high-level treatment requirements, and eliminate most special treatment requirements, including the quality assurance requirements in Appendix B to 10 CFR 50; the inservice inspection and testing requirements for most SSCs within the scope of 10 CFR 50.55a; equipment qualification requirements in 10 CFR 50.49; most maintenance requirements in 10 CFR 50.65; reporting requirements in 10 CFR 50.72 and 73; and seismic qualification testing requirements in 10 CFR Part 100. For RISC-4 SSCs, the proposed rule would eliminate a similar list of special treatment requirements, where applicable, and not specify any high-level treatment requirements.

In lieu of the eliminated special treatment requirements for RISC-3 SSCs, the proposed 50.69 rule contains the following treatment requirements:

> The licensee or applicant shall develop and implement processes to control the design; procurement; inspection, maintenance, testing, and surveillance; and corrective action for RISC-3 SSCs to provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety-related functions under design-basis conditions throughout their service life. The processes must meet the following requirements, as applicable:

(i) *Design control.* Design functional requirements and bases for RISC-3 SSCs must be maintained and controlled. RISC-3 SSCs must be capable of performing their safety-related functions including design requirements for environmental conditions (i.e., temperature and pressure, humidity, chemical effects, radiation and submergence) and effects (i.e., aging and synergism); and seismic conditions (design load combinations of normal and accident conditions with earthquake motions);
(ii) *Procurement*. Procured RISC-3 SSCs must satisfy their design requirements;
(iii) *Maintenance, Inspection, Testing, and Surveillance*. Periodic maintenance, inspection, testing, and surveillance activities must be established and conducted using prescribed acceptance criteria, and their results evaluated to determine that RISC-3 SSCs will remain capable of performing their safety-related functions under design-basis conditions until the next scheduled activity; and
(iv) *Corrective Action*. Conditions that could prevent a RISC-3 SSC from performing its safety-related functions under design-basis conditions must be identified, documented, and corrected in a timely manner.

The NRC staff does not plan to prepare implementation guidance for the RISC-3 treatment requirements in 10 CFR 50.69 (other than that provided in the Statement of Considerations) to replace the guidance in regulatory guides, standard review plans, bulletins, generic letters, regulatory information summaries, and information notices applicable to the eliminated special treatment requirements. Further, the staff does not plan to conduct any inspections of the implementation of the treatment processes established by licensees implementing the rule to evaluate the effectiveness of those processes.

RISC-3 SSC Importance

The categorization process will identify SSCs that perform safety-related functions that have a low safety significance on an individual basis. The robust nature of nuclear power plant design results in redundant and diverse means to satisfy most safety functions. Consequently, the individual importance of any particular safety-related SSC will typically be small, and most safety-related SSCs will be ranked as having low safety significance at a nuclear plant. Experience with risk-informed programs has revealed that typically 50 to 80 percent of safety-related SSCs are ranked as low safety significant at nuclear plants. For example, in the proof-of-concept effort, the licensee categorized about 75% of its safety-related SSCs as low safety significant, including main steam isolation valves (MSIVs); all feedwater system valves (including control and isolation valves); valves in the diesel generator air start system; spent fuel pool pumps and valves; most residual heat removal (RHR) system valves; all (but one) valves in the service water system; reactor head vent throttle and isolation valves; most chemical, volume, and control system valves; high pressure safety injection (HPSI) and low pressure safety injection (LPSI) flowpath MOVs; all component cooling water MOVs; containment spray pumps and valves; and most containment isolation valves (including 9 intersystem LOCA valves).

The Statement of Considerations for the proposed rule asserts that the categorization process has been improved since the South Texas review such that only safety-related SSCs with low or negligible significance will be categorized as RISC-3. However, there are no requirements in the proposed rule that would indicate such a significant change in the categorization process. Further, the Statement of Considerations does not discuss the differences between the

previous categorization approach accepted in the South Texas review and a more robust categorization process asserted to be required by the proposed rule.

The categorization process can provide a reliable ranking of safety-related SSCs based on their individual safety importance. However, the categorization process does not eliminate the safety functions required to be performed by SSCs categorized as being of low safety significance. The proposed rule improperly relies on a categorization process that is asserted to rank only safety-related SSCs of low or negligible significance as RISC-3 without adequate consideration of the treatment requirements necessary to provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety functions.

Common-Cause Interactions

Assuming a proper safety significance ranking of SSCs at a nuclear power plant, the safety impact of eliminating treatment requirements and regulatory guidance for most safety-related SSCs depends primarily on the potential for multiple SSCs failing to perform their safety functions when called upon during an accident. The complexity of the categorization process does not allow common-cause interactions among SSCs across system boundaries to be evaluated on a quantitative basis except for a few limited instances (such as specific circuit breakers). NUREG/CR-5485, "Guidelines on Modeling Common-Cause Failures in Probabilistic Risk Assessment," discusses the challenges of modeling common cause failure events in nuclear power plants and provides a set of guidelines to help PRA analysts in this effort. The proposed rule requires that licensees submit information related to their consideration of common-cause interactions as part of their categorization process. However, common-cause interactions also need to be addressed as part of the establishment and implementation of treatment programs. For example, NUREG/CR-5485 indicates that defense strategies for common-cause failures typically include design control; use of qualified equipment; testing and preventive maintenance programs; procedure review; personnel training; quality control; barriers; diversity (functional, staff, equipment); and staggered testing and maintenance. The proposed rule does not provide confidence that defense strategies for common-cause failures will be established as part of the treatment processes for RISC-3 SSCs.

Commercial Practices

In NUREG/CR-6752 (January 2002), "A Comparative Analysis of Special Treatment Requirements for Systems, Structures, and Components (SSCs) of Nuclear Power Plants with Commercial Requirements of Non-Nuclear Power Plants," the Idaho National Engineering and Environmental Laboratory (INEEL) found that normal commercial and industrial practices at nuclear power plants not only vary widely between plants, but apply to a wide range of activities regarding the functionality of balance-of-plant SSCs. A criticism raised regarding the INEEL study is that the use of varying amounts of practices and treatment for commercial SSCs is not relevant because there are no regulatory requirements for that equipment. Once the NRC imposes a regulatory requirement, the criticism asserts that licensee practices will be changed accordingly. The assumption that licensees will change their commercial treatment to satisfy regulatory requirements in 10 CFR 50.69 is only valid if the regulatory requirements are sufficiently clear to ensure that licensees understand that the treatment must be consistent with the categorization process assumptions. Further, licensees might have widely varying levels of expertise in determining which specific commercial practice needs to be applied to low-risk

safety-related SSCs that would be treated under commercial practice according to 10 CFR 50.69. For example, the INEEL study found that licensees base the amount of treatment applied to balance-of-plant SSCs on their relationship to power generation. Therefore, a licensee might apply specific controls for design, installation, and monitoring of a balance-of-plant SSC that directly supports the generation of electric power, but allow a balance-of-plant SSC that does not directly support power generation to degrade with repairs performed when the SSC is found to not be functional. RISC-3 SSCs associated with the response to plant events (such as containment isolation valves) that do not directly support power generation might be treated as standby equipment with minimal attention under current commercial practices. The results of the INEEL study are consistent with an NRC inspection effort of licensee quality assurance activities applied to nonsafety-related equipment documented in a memorandum dated December 7, 1984, by P. McKee. Further, the conclusions in NUREG/CR-6752 were reinforced by the NRC staff's findings during the review of the South Texas exemption request where the licensee initially planned to apply commercial practices (such as MOV stroke-time testing) to low-risk safety-related SSCs without adequate consideration of the ability to provide reasonable confidence in the functionality of those SSCs. A study referenced by the South Texas licensee in support of its reliance on commercial practice based on an assertion that the reliability of nonsafety-related SSCs exceeded that of safety-related SSCs was found to have several weaknesses, including relying on reported failures over a 25-year time period for nonsafety-related equipment that have minimal testing and reporting requirements. As a result, reliance in the proposed 50.69 rule on general industrial and commercial practices without a clear understanding of the treatment requirements is insufficient to provide confidence in the functionality of RISC-3 SSCs.

Specific Inadequacies in Proposed 50.69 Rule

a. Consensus Standards, Vendor Recommendations, and Operational Experience

Based on the importance of RISC-3 SSCs on a multiple SSC basis, lessons learned from the proof-of-concept effort, and NRC studies of balance-of-plant practices in the nuclear industry, the proposed rule's allowance for each licensee to develop unique methods based on their individual levels of expertise in SSCs, including design, construction, installation, operation, repair, and replacement, does not provide reasonable confidence in the capability of RISC-3 SSCs to perform their safety functions under design-basis conditions. To resolve this safety concern, the DE staff recommended that the proposed rule include a requirement that the RISC-3 treatment processes meet voluntary consensus standards and to address applicable vendor recommendations and operational experience. Such a requirement was supported by the American Society of Mechanical Engineers (ASME) in its comments submitted on June 17, 2002, that exemption of the inservice inspection and testing requirements in 10 CFR 50.55a for RISC-3 SSCs would be acceptable provided a framework is developed to ensure that risk-informed ASME Code Cases and Codes & Standards are used. In its comments submitted on May 15, 2002, NEI supported a similar requirement to apply applicable codes and standards. At a public meeting between NRC, ASME, and NEI representatives on June 18, 2002, the participants did not object to a requirement for licensees to use applicable voluntary consensus standards in implementing the proposed rule.

In addition to requiring use of applicable voluntary consensus standards, a requirement to consider applicable vendor recommendations and operating experience is necessary in light of

the history of SSC functionality problems where such recommendations and experience were not addressed. For example, NRC Information Notice 95-31, "Motor-Operated Valve Failure Caused by Stem Protector Pipe Interference," reported multiple MOV operational problems resulting from licensee-fabricated valve stem protector pipes. Also, NRC Information Notice 97-32, "Defective Worm Shaft Clutch Gears in Limitorque Motor-Operated Valve Actuators," discussed the failure of a non-safety related MOV as a result of improper refurbishment using parts from a supplier other than the original equipment manufacturer. Similarly, a requirement to consider operating experience is necessary to provide confidence that common-cause problems that might affect multiple SSC functionality are addressed. For example, in the proof-of-concept effort, the licensee initially proposed that it would eliminate all regulatory commitments related to RISC-3 SSCs based on only risk categorization without consideration of operating experience that might have a potential impact on SSC functionality. Similarly, the proof-of-concept licensee initially indicated that RISC-3 electrical equipment exceeding their environmental design life would be assumed to remain functional simply because of their risk categorization.

b. Consistency of Treatment with Categorization

The categorization process assumes a specific reliability for RISC-3 SSCs. In sensitivity studies, a licensee implementing 10 CFR 50.69 would reduce the RISC-3 SSC reliability based on its assumptions for the impact of the reduced treatment. Factors of 3 to 4 for reduced RISC-3 SSC reliability have been discussed in conducting those sensitivity studies. These reductions in RISC-3 SSC reliability continue to assume a very high reliability for the functionality of RISC-3 SSCs. For example, a typical MOV reliability assumption of 99.9% assumed in the categorization process might be adjusted to 99.6% in the sensitivity study evaluating the impact of elimination of special treatment requirements. Although changes in design control associated with paperwork might be considered to result in such small changes in the probability of SSC failure, changes in maintenance (such as not performing preventive maintenance on a vendor-recommended schedule) can have a significant impact on SSC reliability such that the categorization process would not be valid. The proposed rule should require that the treatment processes be consistent with the assumptions credited in the categorization process.

c. Design Requirements

An Option 2 directive specifies that the design of the plant not be changed as part of this rulemaking effort. The NRC staff has interpreted this directive to mean that the design functional requirements and bases for safety-related SSCs are not directly affected by the proposed rule. For example, in the proof-of-concept effort, the staff accepted the proposal by the licensee that RISC-3 SSCs designed to ASME Code provisions could be replaced with SSCs designed to less restrictive codes and standards. However, the licensee also indicated that it planned to apply portions of multiple codes and standards in designing RISC-3 SSCs. The staff considered such hybrid designs of safety-related SSCs to have potential adverse safety implications if installed in a nuclear plant without a history of their performance. To prevent this safety problem from occurring with the implementation of 10 CFR 50.69, the proposed rule should require that licensees follow all of the provisions of the code or standard selected for the design of RISC-3 SSCs. A similar concern relates to the design aspect of fracture toughness of ASME Class 2 and 3 SSCs and parts categorized as RISC-3. The

proposed rule should specify this design requirement because lessons learned from the proof-of-concept effort indicate that licensees might not recognize this aspect of design for replacement SSCs.

d. Design Control Aspects

In the proof-of-concept effort, the licensee did not request exemption for Criterion III, Design Control, of 10 CFR 50, Appendix B, to help support its exemption from other special treatment requirements. In light of the importance of adequate design control, the NRC staff identified the most important aspects of design control described in Criterion III that would continue to allow licensees to have flexibility in implementing 10 CFR 50.69. The staff considered the selection of suitable materials, methods, and standards; verification of design adequacy; and control of design changes as the aspects of design control necessary to provide reasonable confidence in RISC-3 SSC functionality. In its May 15 letter, NEI also suggested rule language specifying design control requirements for selection of suitable materials, verify design adequacy, and control changes to the design. The staff had included the control of installation and post-installation testing under design control to allow the elimination of a separate rule requirement for an installation process. The proposed rule specifies no requirements for the control of installation, including installation activities such as welding or post-installation testing. The proposed rule should include specific aspects of design control for selection of suitable materials, methods, and standards; verification of design adequacy; control of installation and post-installation testing; and control of design changes.

e. Corrective Action

The proposed rule does not specify that corrective action will include evaluation of performance problems with RISC-3 SSCs for generic implications and resolution. Common-cause problems can invalidate the conclusion that treatment reductions for RISC-3 SSCs will not result in a safety concern. For example, improper performance of a RISC-3 SSC resulting from use of inaccurate measuring and test equipment can have widespread generic implications for the functionality of other RISC-3 SSCs. The importance of an adequate corrective action process was recognized in the proof-of-concept effort where the licensee did not request exemption from Criterion XVI, “Corrective Action,” of 10 CFR 50, Appendix B, so as to support its exemption requests. The proposed rule should include a corrective action requirement that the cause of the functionality problems be determined and action taken to address generic implications.

f. Process Control and Assessment

The proposed rule will rely on licensee initiative for providing reasonable confidence in the functionality of RISC-3 SSCs. The proposed rule provides almost no documentation requirements for RISC-3 SSCs. For example, licensees will not be required to maintain any documentation associated with design, procurement, installation, testing, or maintenance associated with RISC-3 SSCs. Licensees will not be required to prepare any written procedures for activities associated with RISC-3 SSCs or maintain any records of those activities. Licensees will not required to perform any audits of the treatment processes to provide confidence that the processes are meeting expectations. Allowing treatment processes for RISC-3 SSCs to be undocumented fails to provide reasonable confidence that activities

related to RISC-3 SSCs will be implemented adequately. For example, some licensees in the past reportedly considered complete disassembly and reassembly of MOVs to be within the skill of the craft which lead to numerous performance problems. The lack of requirements for licensee assessments of the effectiveness of the treatment processes will result in the inability to rely on a licensee's internal processes to oversee its treatment processes. Further, absence of documentation will prevent the NRC from conducting an evaluation of plant safety in the event of the loss of control of SSC functionality by a licensee without significant resource expenditures by the licensee and NRC staff. The proposed rule should require that implementation of the treatment processes and assessment of their effectiveness be controlled and accomplished through documented procedures and guidelines.

g. Control of Procured SSCs

The proposed rule contains no requirements for the control of procured items upon receipt. Improper control and inspection of procured RISC-3 SSCs can result in multiple SSCs being incapable of performing their safety functions if called upon during an accident. The categorization process, and its conclusion that adequate protection of the public health and safety will be maintained, are not valid if multiple SSCs are incapable of performing their safety functions. NEI did not object to the procurement requirement for receipt verification. The proposed rule should include a requirement that, upon receipt, the licensee shall verify that the item received is the item ordered.

h. Feedback

The proposed rule does not require that the performance of RISC- 3 SSCs be evaluated in a timely manner to provide confidence that their performance is consistent with the categorization process assumptions. The proposed rule only requires that RISC-3 performance data be considered to determine whether any performance changes are due to treatment changes, and to make necessary adjustments. The proposed rule does not require that the categorization process assumptions for reliability be assessed either before or during implementation on a timely basis. The proposed rule should require sufficient feedback to provide confidence that the treatment reductions have not invalidated the categorization process and the finding that implementation of the rule continues to maintain adequate protection of the public health and safety.

2. The proposed rule package is inconsistent with the Commission's PRA Policy Statement; the Commission's directives for implementing Option 2 of the NRC initiative to risk-inform the regulations; and the Commission's White Paper on Risk-Informed and Performance-Based Regulation.

The Commission's PRA Policy Statement states that "use of PRA technology should be increased in all regulatory matters to the extent supported by state-of-the-art in PRA methods and data." The actual effect of reduced treatment on the reliability of RISC-3 SSCs cannot be determined in advance of implementation of the rule. However, the proposed rule fails to recognize this fact. The proposed rule should provide confidence that assumptions made in the categorization process of the potential effects of treatment reductions are reasonable; that means are in place to monitor SSC performance and to provide sufficient treatment controls where performance monitoring is not sufficient; and that corrective action will be taken and

feedback will implemented as necessary to maintain the validity of the categorization process and its conclusion that the impact on plant safety from the implementation of 10 CFR 50.69 will be small.

Under Option 2 of the NRC initiative to risk-inform the regulations discussed in SECY-98-300, 99-256, and 00-0194, RISC-3 SSCs need to receive sufficient regulatory treatment such that these SSCs will continue to meet their functional requirements, albeit with a reduced level of assurance. The rulemaking plan provided an example of the hydrogen recombiners and the challenge in specifying adequate treatment requirements in the rule. The proposed rule does not recognize the safety significance of RISC-3 SSCs on a multiple SSC basis, and fails to provide sufficient regulatory treatment for RISC-3 SSCs. The Statement of Considerations for the proposed rule claims that the categorization process has been modified to ensure that SSCs with only negligible safety significance will be categorized as RISC-3. However, no requirements are specified in the proposed rule or described in the Statement of Considerations that would support such a claim.

The Commission's White Paper indicates that risk-informed, performance-based approaches use risk insights, engineering analysis and judgement including the principle of defense-in-depth and the incorporation of safety margins and performance history. The Statement of Considerations indicates that the proposed rule relies on a "cornerstone" of a robust categorization process. With an assumption that the categorization process has been enhanced, the proposed rule is now characterized as a "categorization rule" or, in other words, a risk-based rule. In the White Paper, the Commission states that it does not endorse an approach that is "risk-based" because of heavier reliance on risk assessment results than is currently practicable for reactors due to uncertainties in PRA such as completeness.

The proposed rule should provide sufficient requirements such that the categorization and treatment processes meet the Commission's directives for implementing Option 2 of the NRC initiative to risk-inform the regulations while remaining consistent with the Commission's PRA Policy Statement and White Paper.

3. The rulemaking package does not provide a balanced discussion of this first-of-a-kind regulation that will eliminate most special treatment requirements for most of the safety-related SSCs in operating and future nuclear power plants.

The preparation of the proposed 50.69 rule represents the most significant NRC regulatory action related to the treatment of safety-related equipment at nuclear power plants in many years. The proof-of-concept effort and smaller scale risk-informed treatment programs reveal that most of the safety-related SSCs in nuclear plants will be categorized as RISC-3. The impact of the proposed replacement of the current regulations, regulatory guides, and standard review plan for most safety-related SSCs with a few high-level treatment requirements cannot be determined in advance. As illustrated by the lessons learned from the proof-of-concept effort, incorrect interpretation of high-level treatment requirements by licensees might lead to multiple SSCs being incapable of performing their safety functions. With minimal design and procurement control, general inspection and testing provisions, limited corrective action, and almost no documentation, the implementation of 10 CFR 50.69 will significantly reduce the ability of licensees and regulatory staff to verify the functionality of low-risk safety-related SSCs.

The Commission paper provided with the proposed rule does not discuss the potential safety issues that might result if the categorization or treatment processes fail to meet expectations. While the NRC staff will review the categorization process prior to implementation of 10 CFR 50.69, licensees will implement the treatment processes without staff review. If unacceptable performance is identified for multiple RISC-3 SSCs in the future, it could be difficult to determine the impact of those performance issues on the remaining SSCs, plant safety, and public health and safety, with reduced documentation and records. If a licensee implemented an ineffective treatment process, the inability of multiple RISC-3 SSCs to perform their safety functions might not be identified in advance, and might only be discovered during an accident.

Overall, the potential benefits of focused attention on high-risk SSCs and reduced costs might outweigh the disadvantages of reduced confidence in the capability of low-risk SSCs to perform their safety functions. The Commission paper should provide a balanced discussion of these issues.

4. The Statement of Considerations is inconsistent with the proposed rule, and is misleading in its presentation of the proposed requirements.

The Statement of Considerations for the proposed rule includes numerous instances where NRC expectations are indicated. Many of these expectations were specified as requirements in the July 31 draft of the proposed rule. As discussed above, the requirements were included in the July 31 draft rule as a result of component engineering experience and lessons learned from plant-specific and generic review of licensee treatment programs. A discussion of expectations in the Statement of Considerations that are not connected with requirements in the rule does not provide confidence that licensees will follow the expectations rather than their own interpretation of the general requirements in the rule. Further, the Statement of Considerations is typically used for historical reference and not for daily interpretation of regulatory requirements during nuclear plant operations. Rather than relying on discussion in the Statement of Considerations, the proposed rule should specify the requirements necessary to provide reasonable confidence in the functionality of RISC-3 SSCs, and a regulatory guidance document should describe acceptable methods of implementing the requirements as appropriate.

The Statement of Considerations was originally prepared to support the July 31 draft of the proposed 50.69 rule. Following the significant changes to the draft rule during the management concurrence process, the Statement of Considerations was hurriedly modified in an effort to reflect the proposed rule. As a consequence, the Statement of Considerations contains inaccurate and misleading statements regarding the requirements in the proposed rule. Examples include:

> Section III.1.0, “Categorization of SSCs,” states that RISC-3 SSCs are not significant contributors to plant safety. This statement is accurate for individual RISC-3 SSCs. However, inadequate performance of multiple RISC-3 SSCs can have a significant impact on plant safety.

Section III.2.0, “Categorization Requirements,” of the Statement of Considerations states that the proposed rule will require that the revised treatment applied to RISC-3 SSCs be considered for its potential impact on risk. However, the proposed rule only specifies that the licensee have reasonable confidence that the change in risk is small.

Section III.3.2, “RISC-3 Treatment,” states that the Commission concludes that it would be acceptable to allow ASME Class 2 and 3 SSCs categorized as RISC-3 to meet a voluntary consensus standard. This statement is misleading by implying that the proposed rule contains requirements for the approaches that would be acceptable in lieu of the current ASME Code requirements in 10 CFR 50.55a. Further, Section III.3.2 states that “effective implementation” of the treatment requirements provides reasonable confidence of the capability of RISC-3 SSCs, but the Statement of Considerations does not discuss its reliance on effective implementation of the rule to maintain adequate protection of the public health and safety.

Section III.4.0, “Removal of RISC-3 and RISC-4 SSCs from the Scope of Special Treatment Requirements,” states that it is no longer necessary to have the same high level of assurance that less significant SSCs would perform as specified. However, the sensitivity studies required by the proposed rule may increase the failure rate for RISC-3 SSCs by only a factor of 3 to 4 (for example, a typical MOV might have its reliability reduced from 99.9% to 99.6%). Thus, the categorization process continues to assume a high reliability for RISC-3 SSCs.

Section III.4.3, “§50.55a(f), (g), and (h) Codes and Standards,” states that the proposed rule would not remove provisions pertaining to design requirements established in §50.55a. However, as discussed above, the proposed rule has removed several design requirements.

Section III.5.0, “Evaluation and Feedback, Corrective Action and Reporting Requirements,” states that the proposed rule contains requirements for updating the categorization and treatment processes when conditions warrant to assure that continued SSC performance is consistent with the categorization assumptions. The proposed rule does not contain such requirements for RISC-3 SSCs, but rather only a requirement to consider RISC-3 performance data to determine whether any adverse performance changes are due to treatment, and to make necessary adjustments. Section III.5.0 also states that feedback and adjustment is crucial to ensuring that SSC performance is maintained consistent with the assumptions of the categorization process and its results. However, the proposed rule only requires that changes in performance of RISC-3 SSCs be considered in whether to make changes to the categorization or treatment processes without a timeliness provision. Section III.5.0 also states that taking timely corrective action is an essential element for maintaining the validity of the categorization and treatment processes, but the proposed rule does not contain requirements for evaluations of performance problems with RISC-3 SSCs on a generic basis in a timely manner.

Section III.7.1, “Net Change in Risk is Small,” under Section III.7.0, “Adequate Protection,” states that the proposed rule requires that the potential net risk change from implementation of its requirements be assessed, and these requirements will ensure

that the net risk change is small. However, the proposed rule only requires reasonable confidence that the net change in risk is small.

Section III.7.2, "Defense-in-Depth is Maintained," asserts that defense-in-depth will be maintained simply because the proposed rule requires that defense-in-depth be considered in the categorization process, and relies on the consideration of the defense-in-depth in the facility design basis without addressing the removal of treatment (such as for most containment isolation valves).

Section III.7.3, "Safety Margins are Maintained," states that the proposed rule preserves safety margins. However, the proposed rule only requires reasonable confidence that safety margins are maintained. Section III.7.3 asserts that, because only treatment requirements are relaxed, existing safety margins arising from design technical and functional requirements would remain, but does not address the significant impact that treatment can have on SSC performance and, therefore, safety margins. This section also asserts that the proposed rule will place a limit on how much the reliability of RISC-3 SSCs can change, although such a requirement is not in the proposed rule.

Section III.7.4, "Monitoring and Performance Measurement Strategies are Used," asserts that the proposed rule contains requirements that reports are made to NRC of conditions preventing SSCs from performing their safety-significant functions. The proposed rule does not require generic aspects of corrective action to be addressed, nor does it require safety significant impacts of multiple RISC-3 SSC problems to be reported.

Section IV.2.0, "Draft Rule Comments," asserts that the categorization process has been strengthened such that any individual SSC categorized as RISC-3 is of very low safety significance. No technical basis for this assertion is provided.

Section IV.4.0, "South Texas Exemption as Proof of Concept," states that the NRC has applied the lessons learned from the review of the South Texas exemption request in developing the proposed rule. However, as discussed above, the proposed rule has not applied lessons learned from the proof-of-concept effort. Further, the Statement of Considerations does not include lessons learned from the proof-of-concept effort for the need to specify that 10 CFR 50.69 would not affect the commitment change process approved by the NRC.

Section V.5.2.1, "§50.69(d)(2)(i) Design Control Process," states that a design requirement exists for fracture toughness, but the proposed rule does not indicate that this design requirement for repair and replacement of SSCs is retained. Section V.5.2.1 also states that licensees are responsible for proper installation and post-installation testing of RISC-3 SSCs, including welding and other special processes, as part of design control and other treatment processes. The proposed rule does not contain such requirements.

Section V.5.2.2, "§50.69(d)(2)(ii) Procurement Process," states that the licensee would be expected to conduct activities upon receipt to confirm that the received component is what was ordered. The proposed rule does not contain such a requirement.

Section V.5.2.3, "§50.69(d)(2)(iii) Maintenance, Inspection, Test, and Surveillance Process," states that, for a RISC-3 SSC in service beyond its service life, the Commission expects licensees to have a documented technical basis to determine that the SSC will remain capable of performing its safety function. However, the proposed rule does not contain requirements for documentation of technical bases for RISC-3 SSC functionality, other than as part of the corrective action process. Section V.5.2.3 also states that, as discussed under design control, licensees are responsible for proper installation (including welding) and post-installation testing of RISC-3 SSCs during the maintenance process. As noted, the proposed rule does not contain such requirements.

Section V.5.2.4, "§50.69(d)(2)(iv) Corrective Action Process," asserts that effective implementation of the corrective action process would include timely response to information that might reveal performance concerns for RISC-3 SSCs on both an individual and common-cause basis. However, the proposed rule does not require generic corrective action for RISC-3 SSCs.

Section VI, "Additional potential requirements for public comment," lists changes to the July 31 draft rule that was posted on the NRC website. The Statement of Considerations does not provide a technical bases for those significant changes.

5. The proposed 50.69 rule fails to resolve safety concerns regarding the proposed rule in a sufficient technical manner.

The NRC staff prepared a draft version of the 50.69 rule (dated July 31, 2002) based on the experience and technical expertise of staff members, lessons learned from plant-specific and generic evaluations of risk-informed programs and commercial practices at nuclear plants, and stakeholder input provided in public comment letters from ASME and NEI on an earlier version of the draft rule (dated April 3, 2002). The staff also held several public meetings and workshops, including most recently on June 18, 2002, to discuss the draft rule language. Following the completion of the staff's activities to develop a proposed rule that was technically valid, significant changes were made to the proposed rule during the concurrence process without sufficient technical basis.

Various reasons have been indicated for the significant changes made to the July 31 draft rule. None of the reasons is adequate to support the changes. Examples of those reasons are discussed below:

a. The July 31 draft rule was said to be too detailed to meet Commission expectations. However, the July 31 draft of the proposed rule fully met the Commission's directives for a technically valid rule that provides minimal but sufficient treatment requirements for low-risk safety-related SSCs while applying state-of-the-art PRA methods. Following successful experience with the implementation of the rule as described in the July 31 draft, the NRC could evaluate whether further reductions in treatment for RISC-3 SSCs could be accomplished. Issuance of a less detailed but inadequate rule would result in safety problems as a result of licensees implementing ineffective treatment programs.

b. The July 31 draft rule was said to contain requirements specifying how to implement the overall functionality requirement for RISC-3 SSCs. As part of the preparation of the draft rule,

the staff focused on specifying what are the treatment requirements for RISC-3 SSCs. One arguable exception to this focused effort was the requirement for licensees to use of applicable voluntary consensus codes and standards in their treatment processes for RISC-3 SSCs. This particular treatment requirement (whether termed a "what" or a "how" requirement) was based on safety concerns resulting from plant-specific and generic evaluations that licensees might have limited expertise and understanding of design, procurement, installation, maintenance, testing, and replacement of particular safety-related SSCs.

c. The categorization process was said to be improved such that only SSCs of negligible importance will be ranked as RISC-3. Improvements in the categorization process such that less significant SSCs are categorized as RISC-3 are commendable and may allow further reductions in treatment requirements. However, the proposed rule does not require that the categorization process only rank SSCs of negligible importance as RISC-3. During the proof-of-concept effort, the robust nature of the South Texas categorization process was said to result in mostly "vents and drains" being categorized as low risk, but the process was found to also categorize MSIVs and other equipment that together perform important safety functions as low risk.

d. Proposed 10 CFR 50.69 is said to be a "categorization rule" such that only general treatment requirements for RISC-3 SSCs are necessary. The removal of treatment requirements based on the assertion that proposed 10 CFR 50.69 is a categorization or risk-based rule is inconsistent with the Commission's White Paper discussing risk-informed approaches.

e. The technical staff is told to simply trust licensees and PRAs. The staff has been reviewing and approving the application of risk insights in licensee and regulatory programs for many years. The staff trusts licensees to follow the regulatory requirements and the categorization process to rank SSCs according to the relative safety significance. The NRC needs to ensure that regulatory requirements are clear with sufficient specificity such that licensees will implement effective treatment programs that maintain the validity of the categorization process and, thereby, adequate protection of the public health and safety.

ADAMS ACCESSION NUMBER: ML022690484